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EXAMINER
SLOBODYANSKY, E

ART UNIT	PAPER NUMBER
1652	18

DATE MAILED:

08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/470,168

Applicant(s)
Boston et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on May 21, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 15, 16, 18, 20-51, and 58-79 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 15, 16, 18, 20-51, and 58-79 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 17

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

DETAILED ACTION

The amendment filed May 21, 2001 amending the specification to correct typographical errors, canceling claims 1-14, 17, 19 and 52-57, amending claims 15, 18, 24, 27-29, 36, 47-51 and 58 and adding claims 63-79 has been entered.

Claims 15, 16, 18, 20-51 and 58-79 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 47-51 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims 47-51 have not been further treated on the merits.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 15, 16, 18, 21-24, 33-46 and 58-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

Art Unit: 1652

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 15, 18 and 76 are directed to a method for the non-fermentative production of 2-KLG from a carbon source comprising oxidizing the carbon source and reducing the resulting oxidation product to 2-KLG. The dependent claims recite the specific oxidizing or reducing activities, a source thereof, a specific co-factor and specific carbon source. Claims 15 and 18 have been amended to specify a carbon source as any 6-carbon sugars, etc. Claim 76 specifies a carbon source as glucose, gluconate or 2-keto-D-gluconate and "enzymatic derivatives thereof". Therefore, the claims encompass pathways from any carbon source to KLG through any intermediate. The specification discloses oxidation of glucose to gluconate by glucose dehydrogenase and then gluconate by gluconate dehydrogenase and 2-KDG dehydrogenase to DKG. DKG is then reduced to 2-KLG. This pathway is known in the art. The specification fails to describe other representative reactions that produce 2-KLG from any carbon source. Therefore, said reactions are characterized only by the final product, 2-KLG. A starting material, a carbon source, includes a vast genus of different functionally and structurally unrelated compounds. Claims 63 and 73 specify the carbon source and the enzymatic activities but do not specify cofactors. However, the specified enzymatic activities are described by function only. Therefore, the claims

Art Unit: 1652

are drawn to a method of use of a genus of molecules described by broad function. Therefore, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. No common structural attributes identify the members of the genus. Given this lack of description of common structural attributes or characteristics that identify members of the genus of enzymes catalyzing the specific reaction, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 15, 16, 18, 21-24, 33-46 and 58-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing 2-KLG from glucose using glucose dehydrogenase, gluconate dehydrogenase, 2-KDG dehydrogenase and reductase A:F22Y/A272G, does not reasonably provide enablement for producing 2-KLG from any carbon source using any oxidase and reductase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 15, 16, 18, 21-24, 33-46 and 58-79 are so broad as to encompass any combination of oxidase/reductase catalyzing unspecified reactions. Claims 15 and 18

Art Unit: 1652

have been amended to specify a carbon source as any 6-carbon sugars, etc. and "enzymatic derivatives thereof". Claim 76 specifies a carbon source as glucose, gluconate or 2-keto-D-gluconate and "enzymatic derivatives thereof". The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of potential enzymes broadly encompassed by the claims. However, in this case the disclosure is limited to producing 2-KLG from glucose using glucose dehydrogenase, gluconate dehydrogenase, 2-KDG dehydrogenase and reductase A:F22Y/A272G.

The general pathway for producing 2-KLG from glucose disclosed in the specification is known in the art. The specification provides no guidance as to what are other oxidation/reduction reactions that can produce 2-KLG from any source comprising carbon.

The specification does not support the broad scope of the claims which encompass all oxidases and reductases because it is known in the art that enzymes are highly substrate specific. The specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any carbon source as a starting material from which any number of oxidases and reductases produce 2-KLG. Without sufficient

Art Unit: 1652

guidance, determination of enzymes having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear which "enzymatic derivatives thereof" are encompassed by the claims rendering the scope unascertainable.

Claims 20 and 25-32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete as dependent from canceled claim 19.

Claim Rejections - 35 USC § 103

Claims 15, 16, 18, 21-24, 33-46 and 58-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Light et al.

Light et al. (US Patent 4,758,514) teach the pathway glucose - 2-KLG (column 1, lines 16--29). They further teach the production of 2-KLG from glucose by *Erwinia* cell transformed with 2,5-DKG reductase gene (column 17, line 62 through column 20, line 5, Examples 5 and 6). This process comprises enzymatic oxidation of glucose by

Art Unit: 1652

Erwinia into DKG and enzymatic reduction of DKG to 2-KLG. Since enzymes involved in oxidation of glucose to DKG are known in the art it would have been obvious to the one of ordinary skill in the art at the time the invention was made to carry out non-fermentative oxidation of glucose into DKG using purified enzymes or cells transformed with a DNA encoding an enzyme. One would have been motivated to use non-fermentative oxidation of glucose into DKG because it allows a more efficient and convenient production of larger quantities of DKG and KDG compared with the fermentative production.

Claims 15, 16, 18, 21-24, 33-46 and 58-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powers et al.

Powers et al. (US Patent 5,795,761) teach the pathway glucose - 2-KLG. They further teach that a number of microorganisms such as *Erwinia*, *Acetobacter* and *Gluconobacter* can produce 2,5-DKG from glucose and the second group can reduce 2,5-DKG to 2-KLG (column 1, lines 25-61). They teach reductase A:F22Y/A272G mutant (Figure 10, for example) catalyzing conversion of 2,5-DKG to 2-KLG. . Since enzymes involved in oxidation of glucose to DKG are known in the art it would have been obvious to the one of ordinary skill in the art at the time the invention was made to carry out non-fermentative oxidation of glucose into DKG using purified enzymes or

Art Unit: 1652

cells transformed with a DNA encoding an enzyme. One would have been motivated to use non-fermentative oxidation of glucose into DKG because it allows a more efficient and convenient production of larger quantities of DKG and KDG compared with the fermentative production.

Response to Arguments

Applicant's arguments filed May 21, 2001 have been fully considered but they are not persuasive.

It appears that Applicants do not argue the 112, 1st paragraph, rejections except for indicating that the term carbon source "is intended to include all ionization states" (page 8, penultimate paragraph). This is not persuasive because the claims do not limit the source itself not its ionization state.

With regard to the 103(a) rejection, Applicants argue that the both cited references, Light et al. and Powers et al., do not teach every step of the claimed process. Specifically, they do not teach a recycling of the co-factor (pages 9 and 10). However, the references in a 103(a) rejection do not have to disclose the same invention but only to make it obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1652

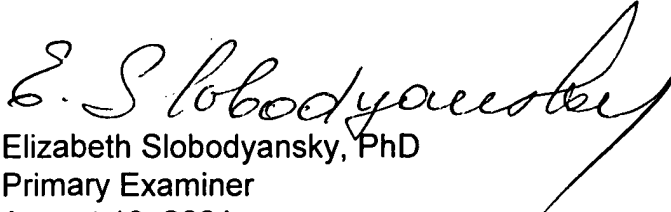
§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner
August 10, 2001